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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,899	09/14/2004	Jari Alander	1291-0216PUS1	8558

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,899	ALANDER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Preliminary Amendment and Applicant's Arguments filed 11/02/06 and the Information Disclosure Statement (IDS) filed 07/20/04 is acknowledged.

Claims 1-5 are pending in this action. Claims 1-5 are rejected.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

* * * * *

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

* * * * *

Claim Objections

Claim 5 is objected to because of the following informalities: Claim 5 recites "a tablet…prepared by a process according to any of claims 1-4". This limitation should instead read as "a tablet…prepared by a process according to any one of claims 1-4".

Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Booth *et al.* (hereinafter "Booth) (WO 00/41676).

Booth ('676) teaches a self-emulsifying drug delivery system and process for producing solid dosage forms of hydrophobic and water-sensitive agents (see page 1, lines 4-11). The system produces a solid dosage form, such as tablets. The self-emulsifying drug delivery system comprises a mixture of microcrystalline cellulose (non-swellable filler), an oily substance, surfactant and water which is then granulated, extruded, spheronized and dried (p. 2, lines 13-24). The pellets thus formed are suitable for compression into tablets or used for filling into capsules (p. 6, lines 11-18).

Suitable surfactants taught include cationic, anionic, non-ionic or amphoteric surfactants (p. 3, line 27 - p. 4, line 2).

Booth differs from the instant invention in that they do not teach the instant selective surfactant selected from fatty acid esters of glycerol and fatty acid esters of polyethylene glycol. However, the claimed surfactants are routinely used and well-known in the art, the Applicant providing no showing of unexpected results attributable to the claimed surfactants claimed. Moreover, the Booth reference explicitly teaches the use of suitable surfactants, including cationic, anionic, non-ionic or amphoteric surfactants (p. 3, line 27 - p. 4, line 2).

The Booth reference also does not identify the particular lipophilic-hydrophilic dispersion, such as an emulsion or liquid crystalline phase. However, the Booth reference vividly teaches a similar process for preparing the self-emulsified drug delivery system using the same components as that instantly claimed. Thus, the recitation of a (micro)emulsion or liquid

crystalline phase is not essential to the instant invention, in that it does not impart patentability to the instant claims as it does not patentably distinguish over the reference teachings of the art.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Booth. Booth teaches a self-emulsifying drug delivery system and process for producing thereof, which yield self-emulsifying solid dosage forms such as tablets.

* * * * *

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remon (WO 94/23700).

Remon ('700) teaches a high release solid preparation and process for preparing thereof for substantially immediate release of an active agent with low or very low solubility (see Abstract); (page 3, line 30 – p. 4, line 13). The reference teaches a granulating medium comprised of solubilizing agents. Preferably the solubilizers is selected among oils, polar co-solvents, fats, solvents, fatty acids and fatty alcohols (p. 4, lines 22-25). Preferred solubilizers taught are polyethylene glycols and polyethylene glycol derivatives such as esters or ethers or mixtures thereof (p. 6, lines 22-24). The reference discloses microcrystalline cellulose as the filler used and pellet forming material (p. 8, lines 29-30); (p. 10, lines 1-11). The granulation medium may be heated prior to addition of the filler. The active ingredient may form part of the granulation medium or may be mixed with the filler prior to the addition of the granulation medium (p. 8, lines 8-18).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Remon. Remon teaches a process for the preparation of active agents having low/very low solubility, whereby the process constitutes use of a granulation medium comprising water, solubilizing agents, fillers, and active agent. The process taught by Remon corresponds to the process as instantly claimed by Applicant.

* * * * *

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz *et al.* (hereinafter "Schwarz") (Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.,27(2000).

Schwarz teaches a self-emulsifying drug delivery system whereby an active material is dissolved or dispersed in a lipid/surfactant phase to form a stable microemulsion. The reference teaches that the formed microemulsion was then granulated with gel-forming water-soluble polymers and other excipients and thereafter dried, milled and compressed to yield traditional tablets. The reference is aimed at improving bioavailability of poorly soluble hydrophobic drugs by providing for self-emulsifying formulations (see pages 824-825).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Schwarz. Schwarz teaches a self-emulsifying drug delivery system whereby an active material is dissolved or dispersed in a lipid/surfactant phase to form a stable microemulsion. The microemulsion is then granulated, dried, milled and pressed to result in controlled release tablet formulations. The process entailed by Schwarz reads on the process presently claimed.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/501,873 ('873 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '873 application also claims a process for preparing a self-dispersing or self-emulsifying tablet, comprising the steps of granulation of a mixture containing a lipophilic substance and a surfactant into granules, cooling the granules, mixing the granules with one or more fillers, sieving the granules and mixing the sieved granules with tabletting aids and compressing said mixture into tablets.

The instant invention differs from the ‘873 application in that it does not comprise a "heated" granulation mixture and does not claim the particular granule size (below 1 mm). However, the additional heating step recited in the '873 application does not distinguish over the instant invention, as both processes claimed yield a self-emulsifying tablet. Moreover, with regards to the claimed particle size of the granules, the determination of suitable or effective granule sizes is within the level of one of ordinary skill in the art, attained by routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

May 12, 20008